3.1 Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
March 2, 2005

Medical Industries America, Inc.
dba Evo Medical Solutions
2636 – 289th Place
Adel, IA 50003-8021

Tel: (515) 993-5001
Fax: (515) 993-4172

Official Contact: Keith Theisen, Director of Engineering

Proprietary or Trade Name: RemRest heated humidifier

Common/Usual Name: Heated humidifier

Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Predicate Devices: Respironics – RemStar – K010263
Fisher & Paykel – HC 150 – K003973

Device Description:

The RemRest Heated Humidifier is a simple heated humidifier to be used with a CPAP device to provide heated and humidified air to the patient. It operates by a conductive heating surface warming a water reservoir and air passes over the water. The device has the following basic specifications:

Size	13.1" L x 8.4" W x 4.7" H
Weight	2.5 lbs. dry
Water capacity	400 ml (1 2/3 cups)
Power	100-240 VAC 50/60Hz or 1.0 A max.
Heater setting	1-5 (85°F to 149°F / 29.4°C to 65°C)
Humidity Range	30 mg H_2O/l @ 25 lpm
Pressure drop	0.5 cm H_2O @ 40 lpm

Indications:

Indications for Use -- The evo Heated Humidifier is intended to warm and add moisture to the breathing gases for administration to a patient. It is used for patients requiring Continuous Positive Airway Pressure (CPAP) therapy for the treatment of Obstructive Sleep Apnea. The addition of heated humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from the use of a CPAP system. Use only with RemRest 900 series CPAP devices.

Patient Population -- Patients utilizing CPAP devices for OSA and desire to have heated humidification

Environment of Use -- Home, Hospital, and Institutional settings

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
March 2, 2005

Comparison to Predicate Devices:

	RemRest Heated Humidifier	**Predicates**
Attributes		
Indications for use	To warm and add moisture to the breathing gases for administration to a patient. It is used for patients requiring Continuous Positive Airway Pressure (CPAP) therapy for the treatment of Obstructive Sleep Apnea. The addition of heated humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from the use of a CPAP system.	F&P – HC 150 – K003973 Respironics – RemStar with humidifier - K010263 Same
Environments of use	Home, Hospital, Institutional	Same
Patient Population	Patients utilizing CPAP devices for OSA and desire to have heated humidification	Same
Contraindications	None	Same
Technology		
Method of heating	Heated plate	Yes
Temperature controlled	Yes	Yes
Connects between CPAP and patient	Yes	Yes
Thermal cutoff	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed device, RemRest Heated Humidifier, and the identified predicates.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K050990 Third Party Organization: Intertek / Antelle

Third Party's Primary Reviewer(s): Neil Devine

ODE/OIVD Division: DAHD Branch/Team: ARDB

Section 2 – 510(k) Decision

Third party recommendation: SE x NSE ____ Other (specify): ____

ODE/OIVD final decision: SE x NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	x		
b. Extent of pre-submission consultation with ODE/OIVD division	x		
c. Organization and format of review documentation	x		
d. Determination of 510(k) administrative completeness (screening review)	x		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	x		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	x		
g. Rationale for conclusions and recommendation	x		
h. Use of guidance documents and standards	x		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	n/a		
j. Scope of reviewer expertise and use of consulting reviewers	x		
k. Other (specify):			

Comments (explanation of ratings/issues): OK.

Section 4 – ODE/OIVD Assessor Information

Assessed by: [signature] Date: 4/26/05 Tel. No.: 827 4479

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2005

Medical Industries America, Incorporated
C/O Mr. Ned E. Devine
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road,
Boxborough, Massachusetts 01719

Re: K050990
Trade/Device Name: RemRest Heated Humidifier
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: April 18, 2005
Received: April 19, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

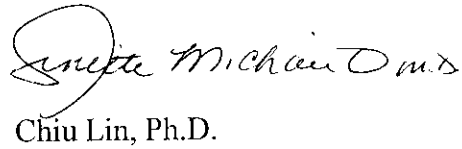
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.3 Indications for Use

510(k) Number: K050990 (To be assigned)

Device Name: RemRest Heated Humidifier

Indications for Use: The Evo Heated Humidifier is intended to warm and add moisture to the breathing gases for administration to a patient. It is used for patients requiring Continuous Positive Airway Pressure (CPAP) therapy for the treatment of Obstructive Sleep Apnea. The addition of heated humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from the use of a CPAP system. Use only with RemRest 900 series CPAP devices.

It is portable and is intended to be used in the home, hospital, and institutional settings.

Prescription Use XX **or** **Over-the-counter use** __
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible]
Infection Control, Dental Devices

510(k) Number: K050990